



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

APR 24 2009

Y.S. Kuo  
General Manager  
Comdek Industrial Corporation  
9F-1, No. 3 Yuan Qu Street, Nan Kang  
Taipei  
CHINA 11503

Re: K083351

Trade/Device Name: Comdek Portable Pulse Oximeter MD-600P  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: II  
Product Code: DQA  
Dated: October 30, 2008  
Received: January 29, 2009

Dear Y.S. Kuo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

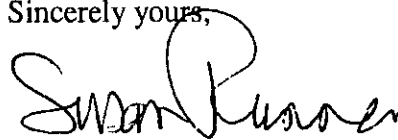
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to <http://www.fda.gov/cdrh/mdr/>.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Susan Runner", is written over the typed name.

Susan Runner, D.D.S., MA

Acting Director

Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number: K083351

Device Name: COMDEK PORTABLE PULSE OXIMETER MD-600P

Indications for Use: The COMDEK Portable Pulse Oximeter MD-600P offers non-invasive continuous and instantaneous monitoring, and provides users with high-level accuracy and a quick measuring response. The environments for use are hospitals, intra-hospital transport, hospital-type facilities and the home. The device is intended for use only with adults.

Prescription Use XXX  
(Part 21 CFR 801 Subpart D)

AND/OR Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON  
ANOTHER PAGE IF NEEDED)

Susan Ruse  
(Division Sign-Off) \_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)  
Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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